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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,506	04/12/2004	Carl G. Hellerqvist	22100-0202 (49530-299673)	3571
23370	7590	07/20/2006	EXAMINER	
JOHN S. PRATT, ESQ KILPATRICK STOCKTON, LLP 1100 PEACHTREE STREET ATLANTA, GA 30309				LI, RUIXIANG
		ART UNIT		PAPER NUMBER
		1646		

DATE MAILED: 07/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/823,506	HELLERQVIST ET AL.	
	<b>Examiner</b> Ruixiang Li	<b>Art Unit</b> 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 25 May 2006 and 14 April 2006.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 82-89 and 97-103 is/are pending in the application.  
4a) Of the above claim(s) 84 and 101 is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 82,83,85-89,97-100,102 and 103 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on 12 April 2004 is/are: a)  accepted or b)  objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 11/01/2004 .

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other:

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group II, drawn to an antibody that recognizes the polypeptide of SEQ ID NO: 8, in the reply filed on 04/14/2006 is acknowledged. The traversal is on the ground(s) that the restriction requirement does not limit the scope of claims 82-102 to the inventions identified as Groups I-IV, or a combination thereof. The examiner notes that the restriction requirement restricts the claims into four distinct inventions. A claim within each invention group, including the generic claim 82, will be examined in its full scope. It is also clarified that claims 84 and 101 are drawn to a non-elected invention.

The requirement is still deemed proper and is therefore made FINAL.

2. Applicants' preliminary amendment filed upon 05/26/2006, 06/19/2004, and 04/12/2004 have been entered in full. Claims 82, 83, 85-89, 97-100, 102, and 103 are pending and under consideration. Claims 84 and 101 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

### ***Drawings***

3. The drawings filed on 04/12/2004 are accepted by the examiner.

### ***Information Disclosure Statement***

4. The information disclosure statement filed on 11/01/2004 has been considered by the Examiner and a signed copy of form PTO-1449 is attached to the office action.

***Objection to the Disclosure***

5. The specification is objected to because it fails to update the status of its parent application 09/359,167, which has now been issued as PAT 6,803,448.

***Claim Rejections—35 USC § 101***

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 82, 83, and 85-89 are rejected under 35 U.S.C. 101 because the claims invention is directed non-statutory subject matter.

Claims 82, 83, and 85-89, as written, do not sufficiently distinguish over an antibody that exists naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of “isolated” or “purified”.

***Claim Rejections—35 USC § 112, 1<sup>st</sup> paragraph***

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 82, 83, 85-89, 97-100, 102, and 103 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an antibody or a fragment thereof that binds the mammalian GBS toxin receptors set forth in SEQ ID NO: 4 and SEQ ID NO: 8, does not reasonably provide enablement for an antibody or a fragment thereof, wherein the antibody or the fragment thereof recognizes any other mammalian GBS toxin receptors or a fragment of a GBS toxin receptor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors that are considered when determining whether a disclosure satisfies enablement requirement include: (i) the quantity of experimentation necessary; (ii) the amount of direction or guidance presented; (iii) the existence of working examples; (iv) the nature of the invention; (v) the state of the prior art; (vi) the relative skill of those in the art; (vii) the predictability or unpredictability of the art; and (viii) the breadth of the claims. *Ex Parte Forman*, 230 USPQ 546 (Bd Pat. App. & Int. 1986); *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

The claims are drawn to an antibody or a fragment thereof, wherein the antibody or the fragment recognizes a mammalian GBS toxin receptor or a fragment thereof. The claims are overly broad because the claims recite "GBS toxin receptor" and "a fragment". There is no structural limitation for the GBS toxin receptor; there are no structural and functional limitations for the fragment of the GBS toxin receptor. Since a fragment of a polypeptide can include a single amino acid, the claims can be

reasonably interpreted to include any substantially purified polypeptide that is smaller in size than the polypeptide of SEQ ID NO: 8. Applicants have taught that human and sheep GBS toxin receptors set forth in SEQ ID NO: 4 and SEQ ID NO: 8, respectively. However, the instant disclosure fails to provide sufficient guidance and/or working examples on how to make and use the recited GBS toxin receptors and fragments thereof. Since the disclosure fails to describe the conserved structure for the binding domain of GBS toxin receptor, it is unpredictable whether a fragment of GBS toxin receptor, for example, SEQ ID NO: 8, maintains the activity of the full-length receptor. It would require large quantities of experimentation to practice the claimed invention. The prior art does not provide any information on how to make and use any GBS toxin receptors or fragments thereof.

Therefore, it would require undue experimentation for one skilled in the art to make and use the GBS toxin receptors and fragments thereof. Consequently, it would require undue experimentation for one skilled in the art to make and use an antibody or a fragment thereof that binds the GBS toxin receptors and fragments thereof.

Moreover, claim 97 is drawn to a composition comprising a reagent for detection of GBS toxin receptor or the fragment thereof. There are no structural and functional limitations for the reagent. There is no disclosure of the structural and functional characteristics of the recited reagent and the disclosure does not provide sufficient guidance and/or working examples regarding how to make the reagent. Thus, it would require undue experimentation for one skilled in the art to make and

use the reagents.

10. Claims 82, 83, 85-89, 97-100, 102, and 103 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

Claims 82, 83, 85-89, 97-100, 102, and 103 are drawn to an antibody or a fragment thereof, wherein the antibody or the fragment thereof recognizes a mammalian GBS receptor or a fragment. The specification defines "GBS toxin receptor" as "a proteinaceous molecule capable of binding a toxin from Group B  $\beta$ -hemolytic Streptococcus bacteria (GBS), such as CM101" (page 5 of the specification, lines 22-23). The claims do not require that the GBS toxin receptor or a fragment thereof possess any particular conserved structure or disclosed distinguishing feature. Thus, the claims are drawn to a genus of antibodies or fragments thereof that bind to mammalian GBS toxin receptors or fragments thereof.

The instant disclosure of GBS toxin receptors set forth in SEQ ID NOS: 4 and

8 and the nucleic acid that encodes the receptors does not adequately support the scope of the genus of GBS toxin receptors and fragments thereof encompassed in the claims. A description of a genus of cDNA may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The instant disclosure fails to provide sufficient description information, such as definitive structural features of the genus of the GBS toxin receptors and fragments thereof encompassed in the claims. There is no description of the conserved regions that are critical to the structure and function of the genus of the GBS toxin receptors and fragments thereof. There is no description of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. Furthermore, the prior art does not provide compensatory structural or correlative teachings to enable one skilled in the art to identify the encompassed GBS toxin receptors and fragments thereof.

Accordingly, due to the breadth of the genus of GBS toxin receptors and fragments thereof and lack of the definitive structural or functional features of the genus of the GBS toxin receptor and fragments thereof, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the genus of GBS toxin receptors and fragments thereof and thus the antibodies that bind to the GBS toxin receptors and fragments thereof.

In addition, claim 97 recites a composition comprising a reagent for detection of GBS toxin receptor or the fragment thereof. The claim does not require that the reagent possess any particular conserved structure or disclosed distinguishing feature. The disclosure does not provide adequate description of the partial structure, physical and/or chemical properties, functional characteristics of the recited reagent. one skilled in the art would not recognize from the disclosure that the applicant was in possession of a composition comprising such a reagent.

***Claim Rejections—35 USC § 112, 2<sup>nd</sup> paragraph***

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 82, 85-89, 97-99, 102, and 103 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 82, 85-89, 97-99, 102, and 103 are indefinite because they recite "GBS toxin receptor". Such a term is determined arbitrarily without a definitive structure. Others in the field may isolate the same protein and give an entirely different name. Thus, reciting biochemical molecules by a particular name given to the protein by various workers in the field fails to distinctly pointing out what the protein is. Applicants should particularly point out and distinctly recite characteristics associated with the protein, such as a sequence identifier.

Claim 97 is indefinite because it recites "a reagent". The specification fails to define the term unambiguously and thus the metes and bounds of the claim are unclear.

***Claim Objections—Minor Informality***

13. Claims 82, 83, 85-89, 97-100, 102, and 103 are objected to because of the following informality: (i). claims 83, 85-89, 98-100, 102, and 103 depend from canceled claims; and (ii). claims 82, 83, 85-89, 97-100, 102, and 103 recite non-elected subject matter. Appropriate correction is required.

***Conclusion***

14. No claims are allowed.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published

Art Unit: 1646

applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.

*Ruixiang Li*

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July 17, 2006

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